PATENT

Docket No. 103864-140 US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	)	
	)	
McErlean et al.	)	Confirmation No.: 7452
	)	
Serial No. 10/634,991	)	Group Art Unit: 3721
	)	
Filed: August 6, 2003	)	Examiner: Hemant Desai

For: AUTOMATED PRESCRIPTION AND/OR LITERATURE BAGGER SYSTEM ~~AND METHOD OPTIONALLY INTEGRATED WITH AUTOMATED~~ DISPENSING SYSTEM AND/OR AUTOMATED LABELING AND PACKAGING SYSTEM

Assistant Commissioner for Patents
Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. §1.131

We, James G. McErlean, Chih-Jen Leu, and Michael Joseph Szesko hereby declare as follows:

1. We are the co-inventors of the above-referenced patent application, which claims priority to U.S. application number 10/215,249 filed August 9, 2002, which claims priority to U.S. provisional application 60/401,340, filed August 7, 2002.

2. All the work described within this declaration was performed in the United States and Canada.

3. All of the work described within this declaration was performed by us, or on our behalf and under our direction.

4. We have reviewed our records, including the exhibits submitted herewith, and readily conclude that a method/system that places a label on a bag; and a method/system for filling a plurality of prescription orders, as claimed within the subject application, including claims 1-53, was conceived and reduced to practice at least prior to July 26, 2002, i.e., the filing date of U.S. Patent 6,769,228 to Mahar.

5. Attached is a Functional System Description document, entitled "Automated Dispensing System (ADS) Functional System Description for the Bagger" dated at least by April 23, 2001, describing the claimed invention. This document was prepared for Merck-Medco, the assignee of the present invention based on our conception of the claimed invention and under our supervision. Portions of this document not relating to the claimed invention have been redacted to minimize the disclosure of unrelated confidential information.

6. This document clearly indicates that that the invention comprising a method/system that places a label on a bag; and a method/system for filling a plurality of prescription orders, as claimed within the subject application, including claims 1-53, was conceived and reduced to practice at least as early as April 23, 2001.

7. In summary, upon review of our records, of which the above-cited pages are representative, we conclude that at least prior to July 26, 2002, i.e., the filing date of U.S. Patent 6,769,228 to Mahar, we had conceived and reduced to practice the method and system, as described and claimed within the subject application in claims 1-53.

8. For example, we conclude that we reduced to practice prior to July 26, 2002, the subject matter of claim 1, reciting, in combination:

> A system that places a label on a bag, comprising:
>
> a first plurality of rollers contacting a bag film comprising a plurality of bags, each of the bags delimited by a perforation, said first plurality of rollers defining an area through which the bag film is conveyed, and rotating in concert in a first direction to convey the bag film, at least one of said plurality of rollers being driven to convey the bag film;
>
> a printer for printing a plurality of labels, each label containing information corresponding to a particular order, disposed on a backing material;
>
> a second plurality of rollers contacting the plurality of labels and the backing material, said second plurality of rollers defining an area through which the plurality of labels and the backing material are conveyed, and rotating in concert to convey the plurality of labels and the backing material for indicia to be printed thereon; and
>
> a label removal and tamp mechanism that receives at least one printed label containing information corresponding to the particular order, selectively removes the printed label containing information corresponding to the particular order from the backing material, and places the printed label on the bag.

9. In addition, we conclude that we reduced to practice prior to July 26, 2002, the subject matter of claims 2-53.

10. We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that the making of willfully false statements and the like is punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed: _____
James G. McErlean
Dated: 4/14/05

Signed: _____
Chih-Jen Leu
Dated: 4/14/05

Signed: _____
Michael Joseph Szesko
Dated: _____

10. We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that the making of willfully false statements and the like is punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed: _____
James G. McErlean
Dated: _____

Signed: _____
Chih-Jen Leu
Dated: _____

Signed: _____
Michael Joseph Szesko
Dated: _____

Merck-Medco

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PRESCRIPTION DISPENSING CENTER

AUTOMATED DISPENSING SYSTEM (ADS)

Functional System Description

for the

Bagger

For Merck-Medco

CONFIDENTIAL

Dated: April 23, 2001

DOCUMENT REVISION HISTORY

GLOSSARY OF TERMS

OCP	Order Consolidation and Packaging System
BSP	Bottle Stream Order Consolidation and Packaging System
AOC	ALPS Order Consolidation

1. INTRODUCTION

1.1. Scope

1.2. Purpose and Organization

2. OVERVIEW

2.1. ATS Bagger

2.1.1. ATS Bagger Operations Overview

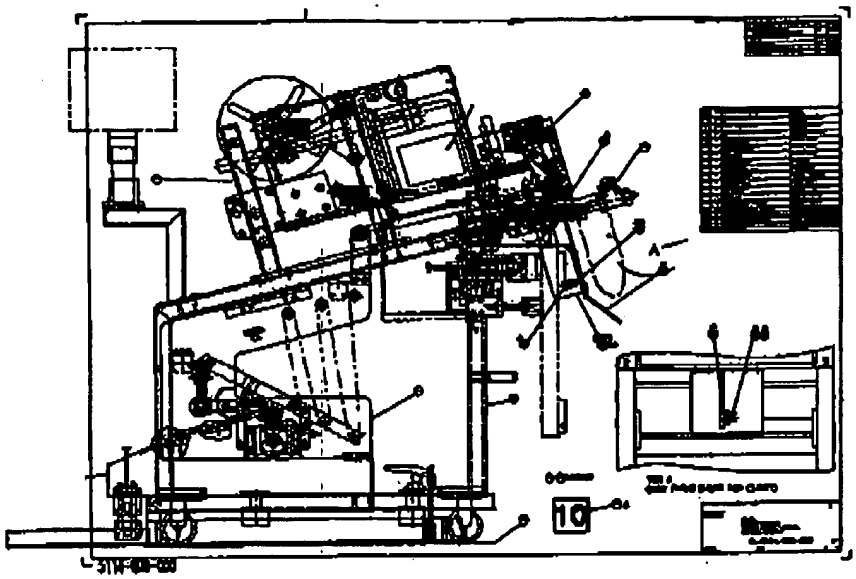
The ATS Bagger is a separate unit that is fully detachable and interchangeable with the OCP's, BSPs.

The ATS Bagger feeds the incoming bags from preloaded fan-folded blank bag stock. The bags are advanced by a servo drive through a series of rollers into the label application position. A SATO label printer from data supplied serially from the control computer prints labels.

Once a bag has had a label applied, it is advanced into the load position, opened using a set of pneumatic "bag open fingers" to open the bag. As the bag is advancing to the bottle load position, a barcode scanner reads the barcode on the printed label to verify the label printed correctly. A cam driven jaw equipped with two rotary actuated fingers and vacuum, grasp the bag and open it allowing product to be placed into the bag.

The lit packs and bottles are then dropped into the bag and the bag sealed by a high temperature seal bar. Once the bag is sealed it is then dropped onto the discharge conveyor for transfer to the mail conveyor or placement into a tote, as appropriate.

2.2. ATS Bagger Layout



3. EQUIPMENT DESCRIPTION

3.1. Infeed Rolls

The infeed rolls pull bag film from the bag box and feed it into the bag feed dancer. The Infeed rollers also maintain tension in the infeed dancers. The tension in the dancers pulls the bag film backward after a bag is dropped and the next bag label is then tamped in the correct position on the bag.

The infeed rolls consist of an upper and lower roller. A variable speed motor drives the lower roller. There are tension control screws on each side of the upper roller to keep the bag film aligned into the dancer. A pneumatic cylinder separates the upper and lower rollers.

3.2. Infeed Dancers

When the dancer is raised by film being pulled through the index rolls, a sensor located above the dancer on the left inboard side turns on the drive motor to the infeed rolls. The infeed rolls feed film into the dancer until the dancer drops down and the sensor turns off the infeed roll drive motor stopping film feed. The rollers are momentarily separated each cycle, allowing the bag film to realign between the rollers.

A manual override pushbutton on the PanelView can be used to power the infeed rolls and feed film, regardless of the dancer position. A second set of manual override pushbuttons on the PanelView can be used to enable or disable the film unwind tension by joining or separating the two infeed rollers.

The infeed dancer accumulates the bag film and provides tension so that the film will not be torn during the bag index. The tension in the dancers pulls the bag film backward after a bag is dropped and the next bag label is then tamped in the correct position on the bag.

A sensor mounted inboard on the left side above the dancer sees the position of the dancer (up or down) and controls the infeed roll drive motor to keep the dancer in the down position (Home). Each time a bag is indexed, the bag film moving through the index rolls pulls up the dancer. This movement causes the sensor to activate the infeed roll drive motor, which feeds more film into the dancer to return the dancer to its lower "Home" position.

The bagger control power must be on for the dancer controls to operate.

3.3. Indexer Rolls

The index rolls pull film from the infeed dancer to index a bag prior to it being opened. The index rolls also retract the film to break the film along the bag perforations.

The index rolls are driven by a Yaskawa servomotor, which is controlled by a 1746-HSRV module in the SLC rack. To perform an index, the SLC commands the servo to 'Home'. When homing, the servo indexes the bag and stops when the bag perforation is detected. When the

'Home' is complete, the SLC commands the servo to do an absolute move to position the bag at the proper position for the jaw grippers to grasp the bag opening.

Once the bag is complete, the index rolls are indexed in the reverse direction. This index breaks the film along the bag perforation.

3.4. Bag Perforation Detection

The bag perforation detection sensor determines the index position of the bag perforation relative to the bag open fingers.

A Keyence FS-V1 fiberoptic sensor is used as the 'Bag Perforation Detection Sensor' to detect the bag perforation. The fiberoptic sensor is connected to the home input on the HSRV module in the SLC rack. When the SLC issues a home command, the film travels under the fiberoptic sensor, toggling the sensor state at the bag perforation. Once the bag perforation is located, the index roll servomotor performs an absolute move to accurately position the bag perforation relative to the bag open fingers so that the bag can be opened.

3.5. Jaw

The bagger moveable jaw functions with the stationary jaw, mounted on the front of the bagger, to pull the bag open after index, close the bag for sealing, and hold the bag to tear the perforation.

The moveable jaw is belt driven through a mechanical linkage (Dog Bone) by a Yaskawa servomotor. A 1746-HSRV module in the SLC rack controls the servomotor.

For safety reasons, power to the jaw is shut off during an "E-Stop" or whenever a guard door is opened.
However, during a "Cycle Stop", the jaw position is held and the bagger can resume its previous cycle following the "Cycle Start" (even if the door has been opened, causing the jaw to lose power). Whenever power to the jaw is restored (after an "E-Stop/Reset" or after closing the door), the jaw is sent to a "Home" position to re-orient the servo. If "Cycle Stop" was pressed prior to opening the door, the jaw will return to its last position and the bagger cycle can resume following a "Cycle Start" (provided that the "E-Stop" has not been pressed). If an "E-Stop" has occurred, the bagger cycle will be interrupted and must be "Reset". It is beneficial to "Cycle Stop" the bagger prior to any manual interruption for a smoother recovery.

The jaw position profile sets the jaw at various positions (distances between the stationary and moveable jaws) during the bagger cycle and controls the timing of movement between positions. Jaw positions include Home (max. open position = 3 3/4"), Ready to Open Bag/Drop Bag (2 5/8"), Opening Bag/Seal Bag/Snap perforation (closed position = 1/8"), and Open Bag (3 ½").

3.6. Seal Bar

The seal bar seals the bag closed after filling.

The temperature controller heats and controls the heater element, via the RTD, to maintain the seal bar at a specific set point temperature (approx. 350 – 420 deg. F) sufficient to melt the plastic bag film. During the Seal and Drop cycle, the moveable jaw closes and squeezes the bag between the stationary jaw and the jaw rubber. While the bag is squeezed, the regulated extend seal bar valve powers an air cylinder to push the hot seal bar forward (fixed ½"stroke), pressing the bag film into the jaw rubber. The seal bar remains extended for a fixed dwell time (fixed ¼ sec. in the SLC), causing the bag material to melt and fuse together. The seal bar is then returned to its rest position. A proximity sensor mounted on the side of the air cylinder verifies that the seal bar has moved properly during the cycle.

3.7. RTD Heater Element

The temperature controller, RTD, and heater element maintain the seal bar at the setpoint temperature.

The setpoint temperature is manually entered into the temperature controller, which compares the temperature of the RTD to the set point temperature. Power from the temperature controller is cycled (on/off) through an output contact in the controller to heat the heater element as required to maintain the seal bar temperature at or near the setpoint. A seal bar temperature deviation of +/- 2 deg. from the setpoint causes a "Seal Bar Temp. Out of Range" alarm.

3.8. Bag Open Fingers

The bag open fingers pull the bag open for filling.

Pneumatic valves connected to the SLC control the bag open fingers. As the jaw closes to open a bag, the bag open fingers are timed to dive into the bag perforation while the vacuum assist suction cup located in the center of the moveable jaw simultaneously acts to pull the bag perforation open. As the jaw moves to open the bag, the fingers close down on the bag perforation and hold it against the jaw rubber.

The bag open fingers and axle are charged with 24 VDC and are electrically isolated from ground by a rubber (Lovejoy) coupling at the driven end, and a Teflon bearing mount in the middle and at the handle end. Spring loaded pins ("Loss of Grip" sensors) under the fingers provide a path to ground for the 24 VDC signal indicating that bag material is not present under the fingers and that the bag is not properly opened. During the bag open cycle, the bagger will try up to three times to properly open the bag and then eject the bag if unopened (or splice) and index a new bag to begin the cycle again. If bag material slips out from under the Finger during the filling cycle, allowing a path to ground for the 24 VDC signal, a "Loss of Grip" alarm will be generated.

3.9. Bag Spreader Fingers

The bag spreader fingers help to hold the back of the bag open as the lit and bottles are dropped and keep the bag seal area spread to prevent seal wrinkles.

The bag spreader fingers are controlled by pressure regulated pneumatic valves connected to the SLC. As the bag open fingers are opening the bag, the bag spreader fingers activate to keep the outside edges of the bag open to maximize the opening available for product to drop into the bag.

The spreader fingers stay open as the bag is sealed to prevent seal wrinkles, and close (return to center "Home" position) as the jaw begins to open to complete the Seal and Drop cycle.

3.10. Bag Inflation

Bag inflation air inflates the bag after it has been opened so it can be filled with product.

A small air jet in the bottom of the bagger front plate directs air into the bag after the bag has been opened. This air is used to "inflate" the bag prior to dropping the lit pack. The air jet is supplied with air from the "HPLV" (high-pressure, low volume) valve.

After the bag has been opened, inflation air blasts for approx. ¼ sec.

3.11. Label Dancer

The label dancer controls label tension into the printer.

The label dancer accumulates labels between the label roll and the printer. During the print cycle, labels are pulled under spring tension from the dancer, causing it to drop. The dancer moves off the "Stop" cam and the SLC enables the label drive motor. The label drive motor, connected by belt to the label roll, supplies labels into the spring loaded dancer, causing it to rise until the dancer "Stop" Cam contacts a limit switch to stop the label drive motor.

3.12. Printer

The printer prints the correct label for the order.

In "Run mode" the Comm Node communicates label data to the printer. In "Maintenance mode", label data (test label) is communicated to the printer by the Basic module in the SLC. The SLC has a digital output to trigger the start of a print cycle.

At the start of the print cycle, the printer drive rolls "back feed" the label approx. ¼" to allow printing of the leading edge, then pull the label forward from the label dancer and across the print head at 6"/sec. After label data has been transferred to the printer and the SLC triggers the print cycle, the printed label exits the printer at the scraper bar, where the label backing material is stripped and accumulated on the label take-up roll, while the label is pushed onto the tamp pad.

3.13. Tamp Pad

The tamp pad stages the printed label and applies it to the bag.

As the printed label is pushed out of the printer and slides onto the tamp pad, the air assist blow tube, powered by the label air assist valve, supplies a cushion of air directed up from underneath the label to pin it against the tamp pad. A grid arrangement of holes under the tamp pad, supplied with constant vacuum, becomes sealed when the label reaches the end of travel (label "parks") and applies vacuum to the label, holding it to the tamp pad. Following the move to snap servo move, the label is tamped onto the bag by an air cylinder driven by the printer tamp valve. Upper and lower proximity sensors on the tamp pad air cylinder sense tamp movement.

3.14. Bar Code Scanner

The bag barcode scanner verifies that the correct printed label has been tamped onto the bag.

At the start of the index bag cycle, the bag scanner turns on. As the bag and printed label are indexed under the scanner, a "Read" or "No Read" is recorded and the scanner turns off.

The bag scanner is not used during "Maintenance" mode operation.

3.15. Docking System

The docking system properly positions and secures the bagger in the OCP station and allows interchangeability of baggers between stations.

The pre-positioned floor track guides the bagger into position relative to the "Z" plate. Once the bagger is front clamped to the track, it can be easily "Docked" using the onboard hand crank. After "Docking", down clamps hold the bagger to the track to minimize vibration.

The docking limit switch "E-Stops" the bagger when the bagger is "Undocked". Connect the DH+ connector, printer cable, communication cable, power cords and air line.